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Attorney's Docket No. PP17201.018 (035784/277291)

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re: Shirley *et al.*

App No.: 10/821,333

Filed: April 9, 2004

For: HSA-FREE FORMULATIONS OF INTERFERON-BETA

July 9, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT  
CITATION UNDER 37 C.F.R. § 1.97**

Attached is a list of documents on form PTO-1449. It is requested that the Examiner consider these documents and officially make them of record in accordance with the provisions of 37 C.F.R. § 1.97 and Section 609 of the MPEP. By submitting the listed documents, Applicant in no way makes any admission as to the prior art status of the listed documents, but is instead submitting the listed documents for the sake of full disclosure.

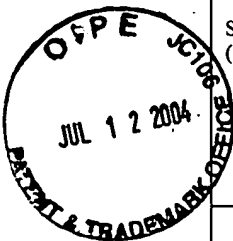
Applicants wish to bring to the Examiner's attention WO 02/34791A2 listed as Cite No. 41. This published PCT International Application corresponds to copending U.S. Patent Application No. 10/035,420, filed October 25, 2001.

All listed documents are attached, except those that were supplied in, or cited by the Office during prosecution of, parent Application No. 10/035,397, filed October 25, 2001. Since the benefit of this application was claimed under 35 U.S.C. 120, no copies need to be furnished in accordance with 37 C.F.R. 1.98(d); however, copies will be furnished on request.

Respectfully submitted,

Leslie T. Henry  
Registration No. 45,714

<p><b>CUSTOMER NO. 00826</b> <b>ALSTON &amp; BIRD LLP</b> Bank of America Plaza 101 South Tryon Street, Suite 4000 Charlotte, NC 28280-4000 Tel Raleigh Office (919) 862-2200 Fax Raleigh Office (919) 862-2260</p>	<p style="text-align: center;"><b>CERTIFICATE OF MAILING</b></p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on July 9, 2004.</p> <p style="text-align: center;"> Polly P. Burton</p>
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Substitute for form 1449A/PTO  
(Revised 10/2001)

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

### Complete if Known

Application Number	10/821,333
Filing Date	April 9, 2004
First Named Inventor	Shirley
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	PP17201.018 (035784/277291)

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### U. S. PATENT DOCUMENTS

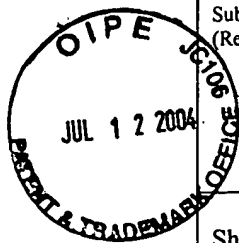
Examiner Initials*	Cite No.	Document Number Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages of Relevant Figures Appear
	1	US - 4,439,181	03-27-1984	Blackshear, P., <i>et al.</i>	
	2	US - 4,462,940	07-31-1984	Hanisch, W. H., <i>et al.</i>	
	3	US - 4,465,622	08-14-1984	Nobuhara, M., <i>et al.</i>	
	4	US - 4,605,555	08-12-1986	Sato, M., <i>et al.</i>	
	5	US - 4,605,556	08-12-1986	Sato, M., <i>et al.</i>	
	6	US - 4,647,454	03-03-1987	Cymbalista, S.	
	7	US - 4,675,184	06-23-1987	Hasegawa, K., <i>et al.</i>	
	8	US - 5,004,605	04-02-1991	Hershenson, S., <i>et al.</i>	
	9	US - 5,004,605	04-02-1991	Hershenson <i>et al.</i>	
	10	US - 5,104,651	04-14-1992	Boone, T., <i>et al.</i>	
	11	US - 5,151,265	09-29-1992	Hwang-Felgner, J., <i>et al.</i>	
	12	US - 5,183,746	02-02-1993	Shaked, Z., <i>et al.</i>	
	13	US - 5,609,868	03-11-1997	Lowther, N., <i>et al.</i>	
	14	US - 5,643,566	07-01-1997	Hanisch, W., <i>et al.</i>	
	15	US - 5,762,923	06-09-1998	Gross, G., <i>et al.</i>	
	16	US - 5,763,409	06-09-1998	Bayol, A., <i>et al.</i>	
	17	US - 5,814,485	09-29-1998	Dorin, G., <i>et al.</i>	
	18	US - 6,525,102	02-25-2003	Chen, B., <i>et al.</i>	
	19	US - 20030180253	09-25-2003	Chen, B., <i>et al.</i>	

### FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document Country Code - Number Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	English Language Translation Attached
	20	EP 0 080 879 B1	10-01-1986	Hasegawa, K., <i>et al.</i>		

Examiner Signature		Date Considered	
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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

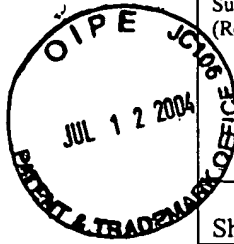


Substitute for form 1449A/PTO (Revised 10/2001)				<b>Complete if Known</b>	
				Application Number	10/035,397
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				Filing Date	October 25, 2001
				First Named Inventor	Shirley
				Group Art Unit	Not yet assigned
				Examiner Name	Not yet assigned
Sheet	2	of	3	Attorney Docket Number	PP17201.003 (035784/240412)

FOREIGN PATENT DOCUMENTS						
	21	EP 0 284 249	09-28-1988	Interferon Sciences, Inc.		
	22	WO 89/02750	04-06-1989	Cetus Corporation		
	23	WO 89/05158	06-15-1989	Cetus Corporation		
	24	WO 90/06762	06-28-1990	Boone, T.C., <i>et al.</i>		
	25	EP 0 164 397 B1	07-04-1990	Wigness, B. D.		
	26	EP 0 410 207 A2	01-30-1991	Coan, M., <i>et al.</i>		
	27	EP 0 410 207 B1	01-30-1991	Coan, M., <i>et al.</i>		
	28	EP 0 133 767 B1	04-03-1991	Noda, M., <i>et al.</i>		
	29	WO 91/16038	10-31-1991	Utsumi, J., <i>et al.</i>		
	30	EP 0 477 386 B1	01-04-1992	Platz, R., <i>et al.</i>		
	31	EP 0 215 658 B1	06-01-1994	Hanisch, W.H., <i>et al.</i>		
	32	WO 95/31213	11-23-1995	Samaritani, F., <i>et al.</i>		
	33	WO 95/31479	11-23-1995	Platz, R., <i>et al.</i>		
	34	WO 95/31213	11-23-1995	Applied Research Systems ARS Holding N.V.		
	35	EP 0 736 303 B1	10-09-1996	Gross, G., <i>et al.</i>		
	36	EP 0 759 775 B1	03-05-1997	Samaritani, F., <i>et al.</i>		
	37	CA 2,304,808	09-23-1997	Dr. Rentschler Biotechnologie GMBH & Co. KG, DE		
	38	WO 98/28007	07-02-1998	Biogen, Inc.		
	39	WO 99/15193	04-01-1999	Dr. Rentschler Biotechnologie GMBH		
	40	WO 99/51272	10-14-1999	Chiron Corporation		
	41	WO 02/34791A2	05-02-2002	Chiron Corporation		

Examiner Signature		Date Considered	
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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## OTHER DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	English Language Translation Attached
	41	BOUBLIK <i>et al.</i> , "Conformation and Activity of Recombinant Human Fibroblast Interferon- $\beta$ ," <i>Journal of Interferon Research</i> , 1990, pp. 213-219, Vol. 10.	
	42	UTSUMI <i>et al.</i> , "Stability of Human Interferon- $\beta$ 1: Oligomeric human Interferon- $\beta$ 1 is Inactive But is Reactivated by Monomerization," <i>Biochimica et Biophysica Acta</i> , 1989, pp. 167-172, Vol. 998.	
	43	The Merck Index, 1989, p. 859.	

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